IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

PENNSYLVANIA EMPLOYEE BENEFIT TRUST FUND, on behalf of itself and others similarly situated, Plaintiffs, v. ZENECA, INC. and ASTRAZENECA PHARMACEUTICALS, L.P., Defendants.	)	Civil Action No. 05-75 (SLR)
LINDA A. WATTERS, Commissioner, Offices of Financial and Insurance Services for the State of Michigan in her capacity as Rehabilitator of The Wellness Plan and in her capacity as Liquidator of Michigan Health Maintenance Organization Plans, Inc., formerly known as OmniCare Health Plan, Inc., individually and on behalf of all others similarly situated, Plaintiff, vs. ASTRAZENECA PHARMACEUTICALS, LP, and ZENECA, INC., Defendants.	)	Civil Action No. 05-196 (SLR)
JOSEPH MACKEN, on behalf of himself and all others similarly situated, Plaintiff, vs. ASTRAZENECA PHARMACEUTICALS LP; AND ZENECA, INC., Defendants.	)	Civil Action No. 05-220 (SLR)

MOTION FOR CONTINUANCE OF JUNE 23, 2005 SCHEDULING CONFERENCE AND FOR A STAY OF DISCOVERY

Defendants AstraZeneca Pharmaceuticals, L.P. and Zeneca, Inc., (collectively "AstraZeneca") hereby move this Court for an Order (a) continuing the joint telephonic scheduling conference currently scheduled for Thursday, June 23, 2005 (D.I. 19), and (b) staying all discovery, including the initial disclosure requirements of Fed. R. Civ. P. 26(a)(1) and the conference of counsel requirement of Fed. R. Civ. P. 26(f), pending this Court's resolution of AstraZeneca's motion to dismiss Plaintiffs' Complaint. In support of this motion, AstraZeneca states the following:

1. NEXIUM® (esomeprazole magnesium) is one of a class of drugs called proton-pump inhibitors ("PPIs"). Nexium was developed and is marketed by AstraZeneca. The Food and Drug Administration ("FDA") has approved Nexium and other PPIs for the treatment of, among other conditions, erosive esophagitis (damage to the lining of the esophagus) and of gastroesophageal reflux (or "acid reflux") disease, the symptoms of which include frequent heartburn. The pioneer PPI was PRILOSEC® (omeprazole), which also was developed and marketed by AstraZeneca.
2. Plaintiffs in the above-captioned cases, and the plaintiffs in cases filed in other jurisdictions by Plaintiffs' and other counsel (see Paragraph 3, *infra*), allege in nearly identical complaints that AstraZeneca deceived the FDA, physicians, and consumers about the relative merits of Nexium and Prilosec. Plaintiffs assert that AstraZeneca gained FDA approval for Nexium by submitting "flawed" studies that failed to compare "equivalent doses" of Prilosec and Nexium. Plaintiffs then assert that AstraZeneca conducted a "massive" advertising campaign that falsely described Nexium as superior to

Prilosec by failing to disclose that at supposedly equivalent doses the two medications are "equally effective." Plaintiffs purport to represent a class of plaintiffs that includes both consumers and third-party payors.

3. AstraZeneca is aware of six other actions in other jurisdictions in which similar, and in some instances identical, complaints have been filed on behalf of overlapping statewide and nationwide classes of Nexium purchasers. One of these cases is pending in federal court (Western District of Arkansas); the other five cases are pending in other state courts (California, Delaware, Florida, and Massachusetts). The cases are:

   a. *Harris, et al. v. AstraZeneca Pharmaceuticals LP, et al.*, United States District Court for the Western District of Arkansas, Case No. 05-3006 (assigned to the Honorable Jimm Hendren), filed by several individuals who seek to represent a nationwide class of individuals who have purchased Nexium;

   b. *Ledwick v. AstraZeneca Pharmaceuticals LP, et al.*, California, Los Angeles County Superior Court, Case No. BC 324518, (assigned to the Honorable Victoria Chaney), filed by an individual who allegedly purchased Nexium and who seeks to represent a statewide class of individuals and third-party payors who purchased Nexium in California;

   c. *AFL-CIO, et al. v. AstraZeneca Pharmaceuticals LP, et al.*, California, Los Angeles County Superior Court, Case No. BC 3232107, (assigned to the Honorable Victoria Chaney), filed by an individual and three associations who seek to represent a statewide class of individuals and third-party payors who purchased Nexium in California;

d. *Teamsters Local 237 Welfare Fund, et al. v. AstraZeneca Pharmaceuticals LP, et al.*, Delaware, New Castle County Superior Court, No. 04C-11-191-CHT (assigned to the Honorable Charles H. Toliver, IV), filed by several union welfare benefits funds who seek to represent a nationwide class of third-party payors;

e. *Prohias v. AstraZeneca Pharmaceuticals LP, et al.*, Circuit Court of the Eleventh Judicial Circuit, Miami-Dade County, Florida, Case No. 05-2433-CA-30 (assigned to the Honorable Victoria Platzer), filed by an individual who purchased Nexium and who seeks to represent a statewide class of individuals and third-party payors; and

f. *Commonwealth Care Alliance, et al. v. AstraZeneca Pharmaceuticals LP, et al.*, Commonwealth of Massachusetts Superior Court, Civil Action No. 05-0269 BLS (assigned to the Honorable Allan van Gestel), filed by individuals, a third-party payor, and an association (represented by the same counsel who represent Plaintiffs in the *Ledwick* and *AFL-CIO* cases) who seek to represent a statewide class of individuals and third-party payors.

4. There are already stays of discovery in place in three of the state actions. In the *Teamsters* case, pending in Delaware Superior Court, plaintiffs have agreed to stay all proceedings in that case in light of the above-captioned actions filed in this Court; a stipulation to that effect was filed on May 4, 2005. In the *Ledwick* and *AFL-CIO* cases, pending in California Superior Court, the Court has stayed discovery until after resolution of AstraZeneca's motions to dismiss the complaints, and motions to strike. In the other cases, while no formal stay has been entered, discovery is not proceeding at this time; in the *Harris* case, pending in the Western District of Arkansas, motions to remand and to

dismiss have been fully briefed; in the *Prohias* (Florida) and *Commonwealth* (Massachusetts) cases, motions to dismiss are being briefed.

5. On May 5, 2005, Plaintiffs filed their Unopposed Motion in Support of Entry of [Proposed] Pretrial Order No. 1 (D.I. 16). Pursuant to [Proposed] Pretrial Order No. 1 ("PPTO-1"), which was negotiated and agreed to between Plaintiffs and AstraZeneca but has not yet been entered by this Court, Plaintiffs and AstraZeneca have agreed, among other things, that:

   a. the above-captioned actions will be consolidated;

   b. the above-captioned actions will be coordinated for pretrial purposes with any individual actions subsequently filed in or transferred to this Court;

   c. Plaintiffs in the above-captioned actions would file a consolidated complaint by May 27, 2005 ("Consolidated Amended Complaint"); AstraZeneca's motion to dismiss will be due July 1, 2005; Plaintiffs' opposition will be due August 5, 2005; AstraZeneca's Reply will be due August 25, 2005;

   d. AstraZeneca will be relieved of the duty to respond to the individual complaints in above-captioned actions;

   e. Plaintiffs' counsel will use their best efforts to coordinate discovery between the above-captioned actions and the state court actions brought by such counsel, including the *Ledwick*, *AFL-CIO*, *Teamsters*, and *Commonwealth* cases; and

   f. Depositions will be cross-noticed in the above-captioned actions and the state court actions brought by Plaintiffs' counsel.

6. Pursuant to PPTO-1, Plaintiffs filed a Consolidated Amended Complaint on May 27, 2005 (D.I. 20).

7. Pursuant to PPTO-1, AstraZeneca intends to move to dismiss Plaintiffs' Consolidated Amended Complaint on or before July 1, 2005, on, among others, the following grounds:

   a. Plaintiffs challenge conduct that is protected by the First Amendment and governed exclusively by federal law. For example, Plaintiffs contend that AstraZeneca submitted the allegedly flawed studies to the FDA as part of AstraZeneca's application for new drug approval for Nexium, that the FDA's approval of Nexium was based in part upon these studies, and that the results of these studies appear on the FDA-approved Nexium labeling. Congress has granted the FDA exclusive authority to evaluate the adequacy of studies submitted to support approval of a new drug, and Plaintiffs' challenge to the FDA's decision is preempted.

   b. Plaintiffs' broad attacks on direct-to-consumer advertising of prescription drugs and on promotion of drugs to physicians are also preempted. Although Plaintiffs complain that such promotion "caus[es] patients to pressure or convince doctors into prescribing expensive and marginally helpful new drugs," and unduly affects the physician's independent medical judgment whether to prescribe a particular drug to a particular patient, Consolidated Amended Complaint ¶ 99, Congress and the FDA have concluded that such promotion is permissible, and such commercial speech is also protected in any event by the First Amendment.

   c. Plaintiffs allege that AstraZeneca falsely promoted Nexium as superior to Prilosec. Although false advertising claims, in the abstract, are not constitutionally protected or preempted, these particular claims are. Although Plaintiffs purport to quote all or portions of four television ads and attach copies

of all or part of twelve print ads in their Consolidated Amended Complaint (*see id.* ¶¶ 112-13, 115, 118, 123-24, 126, 128, 130, 132, 134, 136, 138, 140, 142, 144), only two of the television ads and six of the print ads even reference Prilosec, and none states that Nexium is superior to Prilosec. Plaintiffs therefore are forced to press a novel theory: that all of AstraZeneca's ads are misleading because none contains a disclaimer that Nexium has not been shown to be more efficacious or cost-effective than Prilosec. State law may not require that pharmaceutical companies include statements about the efficacy or cost-effectiveness of a given FDA-approved drug in order to advertise that drug.

At bottom, Plaintiffs' Consolidated Amended Complaint amounts to a challenge both to the FDA's decision to approve Nexium for sale in the United States, and to the standards that Congress has set for approval of new drug applications. The Consolidated Amended Complaint presents issues that may not be litigated in any court, but must be directed, if anywhere, only to the FDA or to Congress.

8. The grounds of AstraZeneca's motion to dismiss are set forth more specifically in AstraZeneca's opening brief in support of its motion to dismiss the original Complaint (D.I. 8) in C.A. No. 05-75 (SLR).

9. AstraZeneca's motion to dismiss raises serious issues and could resolve all or some of the Plaintiffs' claims, thereby eliminating any need for discovery or narrowing the scope of discovery. In addition, the resolution of the motion to dismiss will likely affect the class certification issues raised by the Consolidated Amended Complaint. This Court could prevent the potentially needless expenditure of substantial resources by postponing the entry of a case-scheduling order, and the conduct of expensive discovery, until after

resolution of AstraZeneca's motion to dismiss. *See, e.g., Britamco Underwriters, Inc. v. B & D Milmont Inn, Inc.,* 1996 WL 476624 (E.D. Pa. Aug. 16, 1996) ("It is within the discretion of the court to postpone discovery of issues pending resolution of a potentially dispositive motion, if such a procedure will prevent the waste of time and effort of all concerned and will make more efficient use of judicial resources.") (*citing Coastal States Gas Corp. v. Dept. of Energy*, 84 F.R.D. 278, 282 (D. Del. 1979)).

10. Moreover, the Consolidated Amended Complaint was filed only on May 27, 2005, and pursuant to the PPTO-1, AstraZeneca's potentially dispositive motion to dismiss will not be filed until July 1, 2005. Under these circumstances, AstraZeneca believes that, at this time, it would be both premature and inefficient to hold a scheduling conference or to require the parties to provide initial disclosures.

11. Accordingly, based on the foregoing, AstraZeneca respectfully requests that (a) the joint telephonic scheduling conference, set for June 23, 2005, be continued, and (b) any discovery, including the initial disclosure requirements of Fed. R. Civ. P. 26(a)(1) and the conference of counsel requirement of Fed. R. Civ. P. 26(f), be stayed, pending this Court's resolution of AstraZeneca's motion to dismiss.

12. AstraZeneca asked Plaintiffs to join in this motion. However, despite their agreement in the PPTO-1 (see Paragraph 5.e, *supra*) to use their best efforts to coordinate discovery between the above-captioned actions and the state court actions brought by Plaintiffs' counsel, including the *Ledwick* and *AFL-CIO* cases where discovery has been stayed, and despite the fact that discovery in the four other federal and state cases is not proceeding at this time, Plaintiffs' Proposed Interim Co-Lead Counsel Steve Berman of Hagens Berman Sopol Shapiro LLP would not agree.

MORRIS, NICHOLS, ARSHT & TUNNELL

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May 31, 2005

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RULE 7.1.1 CERTIFICATE

I hereby certify that the subject of Defendants' Motion For Continuance Of June 23, 2005 Scheduling Conference And For A Stay Of Discovery has been raised with counsel for Plaintiffs, but that the parties have not been able to reach agreement.

MORRIS, NICHOLS, ARSHT & TUNNELL

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CERTIFICATE OF SERVICE

The undersigned certifies that on May 31, 2005, a copy of the forgoing was served by electronic filing upon the following counsel of record:

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